



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Kuo et al.

U.S. Serial No.: 10/050,488 ✓

Group Art Unit: 1624

Examiner: V. Balasubramanian

Filed: January 16, 2002 ✓

Attorney Docket No.: CD01351

Location: TC 2900 Legal Instrument Team 1, CMI-5C10

Title: SYNTHESIS OF TEMOZOLOMINE AND ANALOGS ✓

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TECH CENTER 1600/29C

Commissioner of Patents
Washington D.C. 20231

ATTN: Director of Examining Group 1624

PROTEST UNDER 37 C.F.R. 1.291(a)

Sir:

The protester believes that it is improper to grant a patent based on the present application because of issues relating to possible violation of the duty of disclosure under 37 C.F.R. 1.56. For example, applicants failed to inform the Examiner that it been well known in the art that temozolomide could be used to treat cancer. In particular, Shering-Plough has obtained several patents on methods of using temozolomide to treat cancer, e.g. U.S. Patent Nos. 6,346,524; 6,333,333; 6,316,462; 6,251,886; 6,096,757; 5,942,247; 5,939,098; and 5,824,346. Applicants also failed to inform the Examiner that one of ordinary skill in the art would be strongly motivated, based on the teaching of these shering-plough patents, to synthesize temozolomide using the well-known "one step diazotization coupling process" as disclosed in, e.g., U.S. Patent No. 3,941,768. The protester notes that MPEP 1901.02(G) requires that issues related to disclosure "may be the subject of a protest under 37 C.F.R. 1.291(a)."

Alternatively, the protest is filed pursuant to MPEP 1901.02(A).

The protestor encloses a list of prior art references which the applicants might have known before the filing of this protest or will know by the filing and service of the present protest.

Moreover, these references include information material to the patentability of all pending claims. The full texts of these references disclosed each and every element of the claimed methods of synthesizing temozolomide. The protester respectfully requests that the present application be withdrawn by applicants or be rejected by the USPTO on the merits.

MPEP 1901.02(G) states that "Protests raising fraud or other inequitable conduct issues will be entered in the application file, generally without comment on those issues. 37 C.F.R. 1.291(b)." If the applicants agree with the protestor's position, they are expected to withdraw the present application. Alternatively, they should submit copies of relevant references and their translations to the PTO for consideration as it would be unfair to the examiner, the protestor and the public if applicants do not have to fulfill its duty of candor. Moreover, it is in Applicants' own interests to do so.

The protestor includes the following list of references for applicants to submit to the USPTO:

1. U.S.P.N. 3,941,768; JP 2000-327648; JP 53-018521; JP 53-034745; JP 53-127413;
2. JP 54-014932; JP 54-041830; JP 54-059283; JP 54-070232; JP 54-070233;
3. JP 54-073737; JP 54-102127; JP 54-130598; JP 55-009654; JP 55-017349.

This protest is being filed anonymously because (1) MPEP 1901.01 states that "37 C.F.R. 1.291 does not require that the principal be identified," and (2) the protestor is not allowed any further participation in the examination process.

The protester hereby certifies that a copy of the protest is mailed, via first class mail postage prepaid to:

Shering-Plough Corporation
Patent Department (K-6-1, 1990)
2000 Galloping Hill Road
Kenilworth, NJ 07033-0530

In addition, two copies of the protest are included herein. Please forward a copy to Shering-Plough if it does not receive its copy.

Protestor hereby certifies that further protests against Schering-Plough's patent applications will be filed to counter Schering-Plough's over-reaching behavior in seeking patent protection to subject matter that is already in the public domain. In addition, the present protest will be released to the public on the filing date in case Schering-Plough obtains a patent without taking the present protest into consideration and tries to enforce it later against a generic drug company in order to maintain its monopoly.

In addition, the present protest serves the purpose of informing the public that Protester believes that U.S. Patent Nos. 6,346,524; 6,333,333; 6,316,462; 6,251,886; 6,096,757; 5,942,247; 5,939,098; and 5,824,346 all issued to Schering-Plough are likely to be invalid as either being anticipated by or rendered obvious by (1) Br. J. Cancer, Vol. 65, pp. 287-291 (1992); and/or (2) Eur. J. Cancer, Vol. 29A, No. 7, pp. 1045-1047 (1993); and/or (3) Cancer Chemother. Pharmacol., Vol. 27, pp. 342-346 (1991).

Respectfully submitted,

Anonymous protester

Dated: September 31, 2002